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(54) Title: IMMUNOSTIMULATORY POLYNUCLEOTIDE SEQUENCES FOR USE IN PREVENTING AND TREATING RESPIRATORY VIRAL INFECTIONS

(57) Abstract: The invention provides methods of preventing and/or treating infection by a respiratory virus such as respiratory syncytial virus (RSV), particularly reducing infection and/or one or more symptoms of respiratory virus infection. A polynucleotide comprising an immunostimulatory sequence (an "ISS") is administered to an individual which is at risk of being exposed to a respiratory virus, has been exposed to a respiratory virus or is infected with a respiratory virus. The ISS is administered without any antigens of the respiratory virus. Administration of the ISS results in reduced incidence and/or severity of one or more symptoms of respiratory virus infection.

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## INTERNATIONAL SEARCH REPORT

Application No  
PCT/US 01/07839

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K31/711 A61P31/14 C07H21/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K A61P C07H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, SEQUENCE SEARCH, MEDLINE, BIOSIS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 55495 A (DYNAVAX TECHNOLOGIES CORP ;DINA DINO (US); ROMAN MARK (US); SCHWAR) 10 December 1998 (1998-12-10) cited in the application SEQ ID n 2 example 1 claims 1-5,56-63 --- -/--	1-15

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

\*A\* document defining the general state of the art which is not considered to be of particular relevance

\*E\* earlier document but published on or after the international filing date

\*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

\*O\* document referring to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*&amp;\* document member of the same patent family

Date of the actual completion of the international search

10 June 2002

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17/06/2002

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## INTERNATIONAL SEARCH REPORT

Application No  
PCT/US 01/07839

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>MARTIN-OROZCO E ET AL: "ENHANCEMENT OF ANTIGEN-PRESENTING CELL SURFACE MOLECULES INVOLVED IN COGNATE INTERACTIONS BY IMMUNOSTIMULATORY DNA SEQUENCES" INTERNATIONAL IMMUNOLOGY, OXFORD UNIVERSITY PRESS, GB, vol. 11, no. 7, 1999, pages 111-118, XP000938271 ISSN: 0953-8178 cited in the application abstract Sequence of ISS-ODN page 1112, column 1, paragraph 2 Results page 1117, column 2, line 2 - line 7 ---</p>	1-15
X	<p>WO 99 51259 A (UNIV IOWA RES FOUND) 14 October 1999 (1999-10-14) cited in the application claims 1-4,10 page 17, line 24 -page 18, line 24 seq ID n 3, 24, 49, 70, 76, 100, 103 ---</p>	1-4,6-14
E	<p>WO 01 02007 A (KOBAYASHI HIROKO ;RAZ EYAL (US); UNIV CALIFORNIA (US)) 11 January 2001 (2001-01-11) claims page 9, line 7-9 Sequence ID n 3,26,30,32 example 1 ---</p>	1-15
A	<p>ROMAN MARK ET AL: "Immunostimulatory DNA sequences function as T helper-1-promoting adjuvants" NATURE MEDICINE, NATURE PUBLISHING, CO, US, vol. 3, no. 8, August 1997 (1997-08), pages 849-854, XP002188113 ISSN: 1078-8956 cited in the application abstract page 850, column 1, paragraph 2 methods figures 2,3 ---</p>	1-15
P,A	<p>WO 00 62802 A (SMITHKLINE BEECHAM BIOLOG ;DESCHAMPS MARGUERITE (BE)) 26 October 2000 (2000-10-26) claims sequence WD0001 -----</p>	1-4,6-14

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: all partially

Present claims 1-15 relate to an extremely large number of possible polynucleotidic sequences comprising the motifs mentioned in said claims. In particular claims 1 and 2 are so broad that it is impossible to cover all the sequences comprising such a minimal motif. Support and disclosure is to be found, however, for only a very small proportion of the compounds claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, and in particular limited to polynucleotidic sequences comprising the minimal motif RRCGY YCG or RRCGY YCC as in claim 3.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

## INTERNATIONAL SEARCH REPORT

 tional Application No  
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